



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,528	03/07/2001	Mary Rose Woodhead	C70237D1	4127

7590

09/25/2002

GlaxoSmithKline
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER

GUNTER, DAVID R

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/25/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,528

Applicant(s)

WOODHEAD ET AL.

Examiner

Gunter David

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

1. The examiner acknowledges the applicant's election without traverse of Claim 16, drawn to a method for isolating a promoter, in paper number 5 received May 23, 2002. Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

2. Claim 16 is objected to due to minor informalities because each lettered item in the claim is separated from the next by a colon rather than by a semi-colon. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the term "capable of" in the phrase "a promoter capable of driving" is unclear. "Capable of" is not an active method step, and may be interpreted to recite either a property of the promoter or a potential method of using the promoter. The claim should be amended to state that the promoter drives expression rather than that it is capable of driving expression.

In addition, the preamble appears to be missing a word in the phrase "expression of DNA sequences non-climacteric fruit." Correction of the phrase to read "expression of DNA sequences in non-climacteric fruit" or a similar correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bojorquez, et al., Plant Molecular Biology 28(5):811-820, 1995 (hereinafter referred to as "Bojorquez") in view of Mansson, et al., Mol Gen Genet 200:356-361, 1985 (hereinafter referred to as "Mansson") and in

Art Unit: 1634

view of Yang, et al., *Acta Horticulturae Sinica* 21(1):21-25, 1994 (hereinafter referred to as "Yang"). Claim 16 of the instant application recites a method for isolating a promoter a promoter capable of driving fruit-specific expression of DNA sequences in non-climacteric fruit comprising (a) isolating mRNA from ripening blackcurrant fruit; (b) preparing a cDNA library from the isolated mRNA; (c) differentially screening the library from (b) to identify genes expressed during the ripening period; and (d) screening a genomic library with probes prepared from cDNA identified according to step (c) to isolate the corresponding gene and its promoter region.

Bojorquez discloses a method in which RNA was isolated from mango fruit, a cDNA library was prepared, and then screened against RNA isolated from ripe and unripe fruit (page 812, right column, last paragraph through page 813, left column, last paragraph). Genes that were shown to be expressed at a higher level in the ripe fruit were used as probes to isolate the corresponding gene and its promoter region from a genomic DNA library (page 813, right column, third paragraph).

Bojorquez does not specifically disclose that RNA was extracted from ripening fruit, but rather that RNA was extracted from ripe fruit and unripe fruit, however Mannson does teach extraction of RNA from ripening fruit (page 358 left column, first paragraph; also page 358, figures 1A-D). Bojorquez does not teach the use of blackcurrants or other non-climacteric fruit as the starting material for his method. Instead, Bojorquez uses the climacteric mango fruit. However, the method as described by Bojorquez was a common method well known to those of ordinary skill in the art. The method was further known to be adaptable to other fruits as demonstrated by its use by Mannson to identify genes expressed during the ripening of tomatoes

Art Unit: 1634

(Mansson, page 358, figures 1A-D). Therefore, it would have been obvious to one of ordinary skill in the art at the time the application was filed to adapt the method as described by Bojorquez and others by substituting a plant of particular interest for the disclosed starting material.

It was known to those of skill in the art at the time the application was filed that the quantities of nutrients found in blackcurrants change over the course of the fruit's maturation. Yang demonstrates alterations in the content of vitamin C (page 21, figure 1), organic acids (page 23, figure 2), total sugar content (page 23, figure 3), and free amino acids (page 23, figure 4). Understanding the mechanism by which these changes take place would allow manipulation of the ripening fruit to optimize either its nutritional value (vitamin C and amino acids), its flavor (sugar and acid content), or both. Optimizing these factors would result in a fruit which is more desirable to consumers and therefore of greater economic value. This increase in value would provide sufficient motivation to combine the methods of Bojorquez and Mannson as outlined above in order to isolate RNA from ripening blackcurrants to allow identification of a promoter that drives expression of genes involved in fruit ripening for the benefit of using these promoters in a transgenic plant.

Conclusion

5. **No claims are allowed.**

Application/Control Number: 09/800,528

Page 6

Art Unit: 1634

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.



David R. Gunter, DVM, PhD
September 3, 2002



STEPHANIE W. ZITOMER
PRIMARY EXAMINER